NIFEDICOR RETARD®

The active ingredient of NIFEDICOR RETARD is the dimethyl ester of 1,4-dihydro-2,6-dimethyl-4-(0-nitro-phenyl)-pyridine-3,5-dicarboxylic acid (nifedipine). Nifedipine is a calcium antagonist that prevents and reduces coronary artery spams, reduces blood pressure to normal by dilating the peripheral arterioles and diminishes myocardial energy consumption. These properties have led to its use in the treatment of angina and hypertension.

INDICATIONS

Prevention and treatment of acute and chronic coronary insufficiency; angina pectoris; post-infarctual conditions; essential arterial hypertension.

DOSE AND FORM OF ADMINISTRATION

Nifedicor 20 mg retard: one tablet twice a day. An interval of at least four hours must be left between one dose and the next. Tablets should be swallowed whole with a little liquid, preferably far from meals.

CONTRA - INDICATIONS

Ascertained individual hypersensitivity towards the product. The product must not be administered during ascertained or presumed pregnancy.

SIDE EFFECTS

The side effects of nifedipine are usually slight and transient. They are the result of a vasodilatation and rarely it is necessary to suspend the treatment or adjust the dose. Vertigo, hot flushes and headache are the most common unwanted effect. **Less frequent are: hypotension, tachycardia, reduction of myocardial perfusion with increased heart rate and exacerbation of angina crises,** asthenia and peripheral oedema responding to diuretic therapy. The incidence and gravity of peripheral oedema and hypotension are generally dose-dependent and can be relieved by reducing the dose.

Other common side-effects are:

- nausea, heartburn, diarrhoea, constipation, flatulence;
- **hyperglycemia;**
- insomnia, nervousness, tremors, vision disturbances;
- nasal congestion, sore throat, coughing, dyspnoea;
- cramp, stifness of the joints;
- itchiness, urticaria and other skin reactions;
- sweating, shivering, fever;
- sexual difficulties.

There have been occasional reports of slight or moderate increase in alkaline phosphatase, LDH, SGOT, SGPT and as well as cases of hepatitis, thrombocytopenia, purpura, anaemia, leucopenia and swollen gums.

WARNINGS

Owing to the effects of nifedipine on vascular resistance, the patient's blood pressure must be carefully checked, especially at the beginning of treatment and until the maintenance dose has been established. For the same reason, the drug must be used with caution in patients with congestive heart failure, aortic stenosis and those taking ß - blockers or hypotensive agents. The appearance of peripheral oedema in patients with congestive heart failure will require differentation of oedemas attributable to nifedipine from those due to deterioration of left ventricular function.

Blood glucose must be carefully checked. The treatment must be discontinued in the event of hyperglycemia.

NIFEDICOR may diminish the ability to react, especially if taken together with alcohol. This possibility must be taken in to account by drivers of vehicles and people performing operations demanding unimpaired vigilance.

INTERACTION WITH OTHER MEDICAMENTS

Concomitan administration of ß-blockers is usually well tolerated, though hypotension, exacerbation of angina, congestive heart failure and arrhytmia may occur. If digoxin is administered concomitantly with nifedipine, the hematic level of digoxin may increase and should be checked during the first few days of treatment. Concomitant administration of hypotensive agents (methyl-dopa, hydralazine, captopryl, etc.) may lead to severe hypotension.

STORAGE

Protect from light. Keep the product in its own package.

Keep out of the reach of children

PACKAGES

Nifedicor 20 mg Retard - box containing 50 tablets.

Other packages
NIFEDICOR 10 mg: box containing 50 capsules
NIFEDICOR 20 mg: box containing 50 capsules
NIFEDICOR DROPS 20 mg/ml: 30 ml bottle

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